IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 10/574,337
Applicant	: Seong Hwan Cho
Filed	: May 9, 2006
TC/A.U.	: 1614
Examiner	: Geeta Kadambi
Docket No.	: 1751-400
Customer No.	: **06449**
Confirmation No.	: 8934

RESPONSE TO RESTRICTION REQUIREMENT

Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In the Office Action dated July 9, 2008, the Examiner has required an election of a single species with respect to each of (1) active ingredient and (2) polymer.

With respect to (1), the Examiner has indicated that claims 13-16 are deemed to correspond to the active ingredient. In view of the election requirement for an active ingredient, Applicants elect tamsulosin as the active ingredient. Since tamsulosin is a therapeutic agent for prostatic enlargement, the election of tamsulosin reads on claims 14-16 as well as the generic claims 1-13. The election of tamsulosin as a species of (1) active ingredient is made without traverse.

With respect to (2), the Examiner has indicated that claim 2 is deemed to correspond to a type of polymer and that depending on the election made for a type of polymer, the Examiner has further required an election of a single species from claim 5, 6, 10 and 12. Applicants provisionally elect a copolymer of methacrylic acid and ethylacrylate as the polymer (2). Since this polymer is a pH-dependent enteric polymethacrylate copolymer, this election reads on claim 11 as well as the generic claims 1-10 and 12-16. Applicants traverse the election of species requirement as formulated with respect to (2) polymer.

Specifically, Applicants note that the sustained release composition can comprise four different component parts:

> (i) a sustained-release core which contains an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions (claim 1a);
>
> (ii) an enteric film coating layer coated on the sustained release core (claim 1b);
>
> (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer which contains the active ingredient and a hydrophilic polymer for film coating (claim 1c); and
>
> (iv) an outer coating layer coated on the active ingredient-containing film coating layer which contains a film coating polymer (claim 2).

According to claim 2, **the film coating polymer** (claim 2) is selected from the group consisting of a hydrophilic polymer, a hydrophobic polymer, a pH-dependent polymer and a combination thereof. According to claims 9 and 10, **the polymer contained in the outer coating layer** (claim 2) is an enteric polymer selected from the group consisting of cellulosic polymers, polyvinyl polymers, maleic acid vinyl polymers, polymethacrylate copolymers, and combinations thereof.

According to claim 5, **the polymer in the sustained-release core** (claim 1a) is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hydroxymethylcellulose, polyethylene oxide, waxes (Carnauba wax), sodium alginate, povidone, polyvinylalcohol, sodium carboxymethylcellulose, xanthan gum, alginic acid salt and its derivative, and a combination thereof.

According to claim 8 and 10, **the polymer contained in the enteric film coating layer** (claim 1b) is an enteric polymer selected from the group consisting of cellulosic polymers, polyvinyl polymers, maleic acid vinyl polymers, polymethacrylate copolymers, and combinations thereof.

According to claim 12, **the polymer contained in the active ingredient-containing film coating layer** (claim 1c) is selected from the group consisting of polyvinylalcohol, polyethylene-glycol, polypropyleneglycol, acrylic acid copolymer, hydroxypropylmethylcellulose, hydroxypropylcellulose, methylcellulose, ethylcellulose, and a combination thereof.

In view of the above analysis of the component parts of the sustained-release formulation, Applicants submit that the proper election of species for the polymers would be an election of species of a polymer for each of the component parts of the sustained-release formulation, especially since the polymers for each component are not or do not need to be the same. Thus, Applicants submit that the election of species for the polymers should be an election of:

(i) a polymer for the sustained-release core;

(ii) a polymer for the enteric film coating layer;

(iii) a polymer for the active ingredient-containing film coating layer; and

(iv) a polymer for the outer coating layer.

In view of the traversal of the election of species concerning the polymer as initially formulated by the Examiner and request for reconsideration, Applicants elect the following polymers for examination of the component elements of the sustained-release formulation:

(i) hydroxypropylmethylcellulose as the polymer for the sustained-release core which reads on claims 5 and 6 and the generic claims 1-3 and 7-16;

(ii) a copolymer of methacrylic acid and ethylacrylate as the polymer for the enteric film coating layer which reads on claim 11 and generic claims 1-10 and 12-16;

(iii) polyvinyl alcohol as the polymer for the active ingredient-containing film coating layer which reads on claim 12 and generic claims 1-11 and 13-16; and

(iv) a copolymer of methacrylic acid and ethylacrylate as the polymer for the outer coating layer which reads on claim 11 and generic claims 1-10 and 12-16

Applicants request that the Examiner reconsider the election of species with respect to the polymers of the component parts of the sustained-release formulation for the reasons set forth above and examine the polymers of the component parts as elected immediately above.

Early and favorable action on the merits of this application is respectfully requested.

Respectfully submitted,

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